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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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| | |
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| In re Application of | : |
| GIRRARD et al. | :Decision on Petition |
| Serial No.: 10/539,527 | : |
| Filed : 10 July 2006 | : |
| Attorney Docket No.: CNRS.001APC | : |

This letter is in response to the Petition under 37 C.F.R. 1.144 filed on 28 October 2008 requesting reconsideration of the lack of unity requirement mailed 6 September 2007. The delay in acting upon this petition is regretted.

**BACKGROUND**

This application was filed as a national stage of a PCT application and as such is entitled to PCT unity of invention rules.

On 6 September 2007, the examiner set forth a lack of unity requirement which divided the claims into 16 groups and required applicants to elect a single polypeptide for examination.

On 26 December 2007, applicants elected Group I, claims 23-26, 28-32 and 127 with traverse. Applicants elected SEQ ID No 4.

On 29 April 2008, the examiner considered the traversal, stated that the arguments were persuasive but then went on to make the lack of unity determination FINAL.

Claims 33-37, 58-71, 125 and 128 were withdrawn from examination as being directed to non-elected inventions. Claims 23-26, 28-32 and 127 were examined on the merits, as follows:

Claim 31 was rejected under 35 USC 112, 2nd paragraph for indefiniteness.

Claims 23-26, 28-32 and 127 were rejected under 35 USC 112, 1st paragraph for scope of enablement.
Claims 23-26, 28-32 and 127 were rejected under 35 USC 112, 1st paragraph for lack of written description.
Claim 23-25 and 28-31 were rejected under 35 USC 102(b) as being anticipated by Ruben et al.
Claim 23-25 and 28-31 were rejected under 35 USC 102(b) as being anticipated by Jiang et al.
Claim 23-25, 28-31 and 127 were rejected under 35 USC 102(e) as being anticipated by Woolf et al.
Claim 23-25, 28-31 and 127 were rejected under 35 USC 103(a) as being patentable over Kasuya in view of Orr.

On 28 October 2008, applicants filed a response to the Office action and this petition.

**DISCUSSION**

The file history and petition have been considered carefully. Applicants requests that the restriction requirement between Group I and Group IV be withdrawn. This request will be assessed in relation to the claims as currently pending.

The Groups were set forth in the lack of unity determination as follows:

> Groups 1-3. Claims 23-26, 28-32, 127, drawn to a method of ameliorating symptoms of a condition associated with inflammation, said method comprising modulating in a subject the level or activity of the NF-HEV polypeptide or a biologically active fragment thereof, by administering an antisense nucleic acid and altering the expression of a nucleic acid encoding said NF-HEV polypeptide or a biologically active fragment thereof.
>
> Groups 4-6. Claims 33-37, 128, drawn to a method of ameliorating symptoms of a condition associated with inflammation, said method comprising modulating the level of transcription of at least one promoter responsive to an NF-HEV polypeptide or a biologically active fragment thereof wherein the level of a pro-inflammatory cytokine is reduced.

At the onset, it is noted that the lack of unity determination is not fully clear how the Groups I-VI are divided. For purposes of this petition decision, Groups I and III are considered as directed to the method of modulating the level or activity of SEQ ID No 4, while Groups II and V are directed to the method of modulating the level or activity of SEQ ID No 5 and while Groups III and VI are directed to the method of modulating the level or activity of SEQ ID No 6.

Additionally, the lack of unity determination also contained the following text:

NOTE: Should any one of the Groups from 1-2 be elected, Applicants are required to select one polypeptide of specific amino acid sequence as set forth in SEQ ID NO:4-6. Once one polypeptide is selected all other will be withdrawn from consideration.

Applicants must choose a single polypeptide sequence for examination. This is not a species election, but an election of a single invention.

As shown below, currently pending independent claim 23 and independent claim 33 are not limited to the three SEQ ID Nos that the examiner is relying for support of dividing Claim 23 and claim 33 each into three groups:

23. (Currently amended) A method of ameliorating symptoms of a condition associated with inflammation, said method comprising:

identifying a subject having symptoms of a condition associated with chronic inflammation; and

~~modulating~~ reducing in said subject the level or activity of the NF-HEV polypeptide or a biologically active fragment thereof, thereby ameliorating symptoms of a condition associated with inflammation.

33. (Withdrawn) A method of ameliorating the symptoms of a condition associated with inflammation, said method comprising modulating the level of transcription of at least one promoter responsive to an NF-HEV polypeptide or biologically active fragment thereof.

Because the sum of the scope of the groupings is less than the scope of the independent claims, the lack of unity determination within independent claim 23 and within independent claim 33 is incorrect for at least this reason.

Turning now to the merits of the petition, PCT Rule 13.2 states that:

> Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The criteria for determining the concept of "contribution over the prior art" is further discussed in Chapter 10 of the International Search and Preliminary Examination Guidelines:

*Rule 13.2; AI Annex B, Part 1(b)*

> 10.02 Whether or not any particular technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature," is considered with respect to novelty and inventive step. For example, a document discovered in the international search shows that there is a presumption of lack of novelty or inventive step in a main claim, so that there may be no technical relationship left over the prior art among the claimed inventions involving one or more of the same or corresponding special technical features, leaving two or more dependent claims without a single general inventive concept.

Applicants correctly argue that the subject application is a National Phase filing of a PCT, filed in compliance with 35 USC 371, and thus questions of unity must be resolved using the criteria of PCT Rule 13.

Referring to PCT Rule 13.2 and 37 CFR 1.475, applicants urge that Groups I and IV are drawn to methods of ameliorating symptoms of a condition associated with inflammation.

The examiner used the following reasoning to make the lack of unity determination FINAL:

> Since the instant application contains multiple processes (e.g., methods of ameliorating symptoms of a condition and methods of identifying a candidate inhibitor of an NF-HEV polypeptide) it is concluded that the present application lacks unity of invention.

Because Groups I and IV are directed to a method of ameliorating symptoms of a condition, the examiner has provided no basis for maintaining a lack of unity determination amongst Groups I-VI. Group I and IV are directed method claims. Typically, the special technical feature in method claims is found in the active steps, not in the preamble. This petition decision now sets forth reasons why Groups I and IV lack unity of invention.

While both Groups I and IV are drawn to methods of ameliorating symptoms of a condition associated with inflammation, Group I requires the special technical feature of reducing the level or activity of the NF-HEV polypeptide which is not required for Group IV. Group IV requires the special technical feature of modulating the level of transcription of at least one promoter to an NF-NEV polypeptide which is not required for Group I. It is noted that the modulation of Group IV encompasses up-regulation of transcription which may result in increased levels of NF-NEV polypeptide which is not encompassed by Group I. Moreover the reduction in polypeptide activity of Group I may be accomplished by post-translational intervention, which is not encompassed by Group IV.

It is noted that the lack of unity determination must be assessed anew throughout prosecution, in relation to the claims as currently pending. Moreover, MPEP 1893.05(d) provides the following guidance concerning rejoinder opportunities for application filed in compliance with 35 U.S.C 371:

If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04. Any nonelected processes of making and/or using an allowable product should be considered for rejoinder. The examiner should notify applicants of potential rejoinder of non-elected process claims by placing form paragraph 8.21.04 at the end of any lack of unity determination made between a product and a process of making the product or between a product and a process of using the product.

**DECISION**

The petition filed under 37 CFR 1.144 on 09 June 2008 is **GRANTED-IN-PART**.

The lack of unity determination set forth on 6 September 2007 among the Groups I-III is hereby withdrawn.

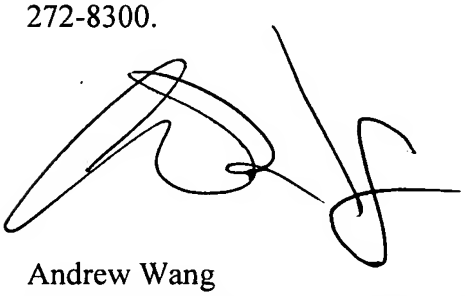
The lack of unity determination set forth on 6 September 2007 among the Groups IV-VI is hereby withdrawn.

The election of SEQ ID No 4 will be treated as an election of species requirement. Should the elected species be found allowable and/or should any generic claim encompasses elected and non-elected species become allowable, the examiner will follow the rejoinder guidance in MPEP 1893.05(d) and 821.04.

The application will be forwarded to the examiner to consider the papers filed on 28 October 2008 and to prepare an non-final Office action consistent with this petition decision which addresses claims 23-26, 28-32 and 127.

Any request for reconsideration of this decision must be filed with TWO (2) MONTHS of the mail date of this decision.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-272-8300.



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